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The purpose of this report is to provide an addendum to the final report of a study to investigate and address enlisted women's needs for basic gynecological and reproductive health education in order to enhance military readiness and general well-being. In the first phase of the study, a needs assessment was conducted in which the methods included: 1) a mail survey of knowledge, attitudes, and practices (KAP) from a random sample of Army and Navy clinicians and chiefs of military medical departments; 2) focus groups with enlisted Army and Navy women and with their health care providers; and 3) a secondary analysis of a national survey of military personnel health related behaviors. Based on the results of these needs assessment data, we have determined implications for enlisted women's reproductive health. These data were used in the fourth year to design and begin development of a culturally appropriate, multimedia CD-ROM and accompanying materials. This intervention was to be tested in military medical clinics in an extension year to determine its ability to change knowledge, attitude, and behavioral intent regarding female reproductive health. This report describes the progress and challenges in the efficacy portion of this study.

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## I. Introduction

The project "CD-ROM Technology to Increase Appropriate Self-Care and Preventive Behaviors Among Army and Navy Women" was initiated as a way to study and address the reproductive health education needs of enlisted Army and Navy women. Not only is the ability of each female soldier to protect and control her reproductive health essential to military readiness, it is important for these women's quality of life. The purpose of the study was to investigate enlisted women's needs for basic gynecological and reproductive health education, from the perspective of military health care providers and enlisted women themselves. Based on the results of the needs assessment, a culturally appropriate, multimedia CD-ROM and accompanying materials were developed. This intervention was then to be tested in military medical clinics.

This report describes the year following the end of project, in which we extended the contract to try to conduct the efficacy study. Although the project ended in July 2001, the USAMRMC approved an extension to the contract for one year, which would end in September 2002. In consultation with the Dr. Patricia Modrow, Science Officer at the US Army Medical and Materiel Command, we are submitting this final report to summarize the activities that took place in this extension year as well as the problems in accomplishing these activities.

## II. Body: Project Progress

The experimental methods and procedures reported here represent a description of the work done to accomplish the last phase of the research project: the efficacy test. The original scope of work included the following 16 tasks:

1. Convene advisory panel
2. Develop needs assessment surveys, provider surveys
3. Conduct needs assessment
4. Conduct focus groups
5. Analyze needs and develop curriculum and multimedia design document
6. Develop multimedia CD-ROM
7. Submit first annual project report
8. Develop accompanying materials and field pocket guide
9. Conduct in-house and expert review of multimedia program
10. Conduct target audience review of multimedia program
11. Set up for intervention
12. Submit second annual project report
13. Begin intervention: rolling recruitment of intervention participants and collection of baseline knowledge, attitudes, and practices (KAP) data
14. Conclude intervention, collect post-intervention KAP data
15. Submit third annual project report
16. Analyze data and assess achievement of technical and behavioral goals
17. Complete final report

Tasks 13, 14, and 16 could not be completed in the original timeframe, although much progress

had been made in gaining IRB approval at the field test sites by the end of the project. As we continued our efforts, we found that problems continued to hamper our ability to gain approval to conduct the research and to actually recruit research participants. In the next section, we describe our efforts by data collection site and the challenges we experienced at each. This section is followed by a description of *the research findings*.

## A. Key Research Accomplishments

### 1. Uniformed Services University of the Health Sciences (USUHS)

We completed IRB approval and sign off by USAMRAA to conduct the efficacy study at USUHS. At the end of the project period, we had recruited 5 active duty enlisted females to participate in the study. We reported these results in the final report, submitted in September 2001.

The students at USUHS were most often officers and were therefore not the target population for the study. Staff at USUHS who were students were not allowed to participate in research studies. This left very few enlisted female personnel, and all who fit the inclusion criteria and agreed to volunteer had already participated in the study. As a result, we did not continue to attempt to collect data in the extension year.

### 2. Walter Reed Army Medical Center (WRAMC)

IRB approval and USAMRAA sign off at WRAMC was also completed by the end of the project period. While a contract extension was being put into place, the attack on the World Trade Center and the Pentagon occurred. At that point, the co-investigator at WRAMC, the Chief of the Department of Psychology, was overwhelmed with bereavement counseling for the families of Pentagon victims and survivors.

After the national security situation stabilized, the co-investigator put staff in place to facilitate data collection efforts. This staff person initiated contacts with medical installation personnel, went to health fairs in the hospital to advertise the study, and invited individual women to participate in the study. Recruitment efforts were largely unsuccessful, possibly because the study was being conducted in the Department of Psychology building, which is separate from the main hospital. The data from the few women who agreed to participate could not be used because no identification number was put on the surveys to link pretests with posttests.

The staff member left WRAMC in July 2002. Since then, the co-investigator has continued to have no success in recruiting participants to volunteer for the study. Other responsibilities have continued to take his time, such as working on a special task force to help law enforcement staff to deal with the Washington area sniper shootings in October 2002.

### 3. Malcolm Grow Medical Center (MGMC)

At the end of the project, MGMC had completed their IRB approval process, but USAMRAA did not sign off on the protocol because they had some changes they wanted made to the protocol, flyer, and consent form.

The process of revising the protocol and consent form was hampered over the following year for several reasons. First, the IRB preferred to have the military co-investigator request any documents and would not communicate with the civilian investigator working on the project. The co-investigator was deployed to Florida, and an associate investigator served as the contact person in her absence. The forms that the associate investigator sent to USAMRAA were not consistent with the protocol originally approved by MGMC but appeared to be the protocol submitted to another efficacy test site (National Naval Medical Center), based on the comments in the review letter from Dr. Adriene King at the Human Use and Regulatory Affairs Office. Efforts to get the appropriate documents forwarded to USAMRAA were stalled because the associate investigator lacked familiarity with the original application process and could not find the documents. Lastly, when the co-investigator returned to MGMC, she also was unable to trace the appropriate documents before the extension period was ended.

### 4. National Naval Medical Center (NNMC)

At the end of the original project time frame, we had engaged a co-investigator and support from the Department of Obstetrics and Gynecology at NNMC. However, the IRB review meeting was not held until November 2001. At that time, the IRB said it would approve the protocol with changes. The revision process began in January 2002 and was completed in February 2002.

In March 2002, NNMC requested a memorandum of understanding (MOU) between NNMC and the University of Maryland. After negotiations between the Clinical Investigations Division (CID) of NNMC and the university Office of Research Advancement and Administration (ORAA), NNMC decided in July 2002 that a Cooperative Research and Development Agreement (CRADA) was a more appropriate way to formalize the partnership between the two organizations on the research project. On September 10, 2002, NNMC informed the co-investigator that the protocol had been approved, and they returned a fully executed CRADA to the University of Maryland.

At this time, the protocol had not yet been reviewed by USAMRAA. The Human Use Office could not review the protocol without an active project, and the extension period had expired. Therefore, no data collection was approved or done.

### 5. Problems in Accomplishing the Efficacy Test Tasks

**Research a low priority in the time of increased emphasis on national security.**

Although our co-investigators were confident in their and their installations' abilities to contribute to the research project, they were directed to take on other duties in response to September 11 and in anticipation of a possible war in Iraq. Though every attempt was made to continue work, the changes in security at the different installations also hampered efforts for a collaborative effort between civilian and military organizations. For example, some research offices refused to communicate with the civilian investigators. The civilian investigators was also at times unable to meet with military personnel in person because of the increased security at the installations made it difficult to travel to them.

**Staffing changes.** This issue was alluded to in the last item, in that duties and situations changed at the different field test sites and hindered having a smooth research operation. As mentioned above, some co-investigators were deployed. Associate and assistant investigators stepped in, but they had little background in the project or in research. Data management was not maintained, and some data were lost because of lack of identification numbers to link pretest and post-test questionnaires. Some co-investigators were stationed in the Washington DC metropolitan area because they or family members were experiencing a chronic disease, such as cancer, and were therefore not always able to make planned appointments.

**Lack of enlisted female personnel.** Besides USUHS, many of the other medical facilities were more likely to serve dependents or officers. At WRAMC, the co-investigator's offices were away from the main hospital, which posed a further barrier to potential volunteers. At USUHS, MGMC, and NNMC, a large proportion of the available enlisted female personnel were coming for prenatal care rather than regular women's health examinations.

**Unequal IRB and contracting procedures.** Some of the IRB reviews sought to revisit the funded study plan, even the title of the original research. After providing further support for the intervention, we were able to gain verbal IRB approval at the NNMC. After that the contractual agreements necessary to partner with NNMC again lengthened an already long process so that approval at the field test site level was only completed by the end of the extension period.

### B. Findings

Despite extending data collection to September 2002, no other participants have completed the study. Therefore, we have no other data to report in addition to the final report dated October 2001.

## III. Reportable Outcomes

In terms of reportable outcomes, this project did not result in any patents or licenses. We have made one more paper presentations at a professional meeting. Because the research is not yet

complete, we have also not yet sought funding for extending the research in this area. A presentation about the project was given at the annual Teaching with Technology conference at the University of Maryland, College Park. The presentation is in Appendix A, and the citation and abstract is as follows:

- Odam, K.S., N. Atkinson, and R.S. Gold. 2002. Preventive Maintenance: Using Interactive reproductive health education to improve knowledge, communication skills, and health behaviors among women. Presented at the Teaching with Technology 126th annual meeting, November, Washington, DC.

The number of women in the U.S. Armed Forces is increasing, and there is a growing concern about their health needs, particularly in regard to unintended pregnancies, STDs, and other preventable gynecological conditions. Many studies have examined the unique health concerns of military women, but few studies have tested interventions for addressing these concerns. In response to the Defense Women's Health Initiative, students and faculty of the Public Health Informatics Laboratory developed an interactive reproductive health educational program to enhance enlisted women's self-care and care-seeking behavior.

The primary objective of this presentation was to illustrate how interactive technology can be used to enhance or complement existing reproductive health education methods. Preventive Maintenance uses tailored feedback, video briefings, educational content related activities, and skill building activities to allow students learn how to protect and maintain their personal health. The activities presented in this CD-ROM can be applied in a variety of ways to respond to teachers' needs for exiting, innovative and context-appropriate classroom health education strategies.

## V. Conclusions

The conclusions related to the needs assessment and intervention development phases of the research project are outlined in the final report. Drawing conclusions before the efficacy study is complete continues to be premature, since the evaluation is not complete. Instead, we will use this section to focus on the conclusions and implications that have emerged as the result of the difficulties experienced in the efficacy test phase of the research.

Despite the challenges to doing research in times of increased national security, these materials were created to alleviate some of the problems that occur during deployment and troop mobilization. We heard throughout the project that effective materials are needed and that good materials are not being made available because of lack of knowledge about them. Evaluation research is needed so that—if the materials are found to be effective—they can be promoted to unit leaders coping with the needs of female active duty personnel.

We also heard in discussions with commanders that Internet access is becoming ubiquitous in the field and on shipboard. Therefore, CD-ROM technology or Internet-based programs could continue to serve the health education needs of those on deployment for whom the ability to have personal care and health education is limited.

Although the project's contract period is complete, we plan to pursue our plans to complete some level of evaluation. Too much work has gone into research and development and to engaging a cross-service team of investigators. We plan to continue the following activities:

- Finalize agreements with military co-investigators who will participate in the efficacy test of the application;
- Conduct the efficacy test;
- Analyze efficacy test data and report the findings;
- Revise the intervention based on the efficacy test findings;
- Promote the application to appropriate military commanders; and
- Apply the lessons we have learned to other interactive health communication applications for reproductive health.

## APPENDIX A:

## Presentation at 2002 Teaching with Technology Conference

# Preventive Maintenance:

Using interactive reproductive health education technology to improve knowledge, communication skills, and health behaviors among women.

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# Purpose

- Growing concern for military women's health needs.
  - Unintended pregnancies, STD's and other preventable gynecological conditions.
- Many studies examine women's unique concerns in the U.S. Armed Forces.
  - Few have tested interventions that would address these concerns.

# Objectives

- To test an interactive reproductive health education program among enlisted women representing the Army, Navy, and Air Force with the goals to:
  - ◆Improve personal health knowledge.
  - ◆Develop communication skills with providers and partners.
  - ◆Enhance their self-care and care seeking behavior.

# Why Do We Need This?

- In response to the Defense Women's Health Initiative Project.
- Priority Areas:
  - ◆ Unintended pregnancy
  - ◆ Sexually Transmitted Diseases
  - ◆ Vaginal and Urinary Tract Infections
- **Key message**: Take action now to maintain and protect your reproductive health.

# Educating Women:

- Interactive technology can be used to enhance or complement existing reproductive health education methods.
- Instructional Design of "Preventive Maintenence."

# Video Briefing

- Learning activities meet educational needs for exciting, innovative and context-appropriate health education strategies.

## Activities and Library

- Basic Training:
  - Anatomy & physiology
  - Contraception
  - Vaginal infections
  - Hygiene supplies
  - Costs of pregnancy
- Field Exercises:
  - Communicating with partners
  - Communicating with health care providers
- Resource library:

## Opportunities for Use

- Consumer Health.
- Women's Health.
- Human Sexuality.
- Patient Education.

# Implications

- Integrated activities can be used on their own or to enhance classroom activities.
- Promotes Interactivity in various settings
- Tailored feedback offers decision support

# Contact Information


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